REMARKS SECTION

STATUS OF THE CLAIMS

Claims 1-13 are pending in the application.

Claims 2,4,6,8 and 11 were rejected under 35 USC§102(e) as being anticipated by Harish et al. '437, and claims 2,4,6 and 8 were rejected as being anticipated by Durgin published application No. US 2002/0052653 A1 (Durgin).

Claims 2,6 and 8 were rejected under 35 USC§103(a) as being unpatentable over Marotta et al. '930 in view of Melican et al. '323.

Claims 2,4,6,8 and 11 were rejected under 35USC§112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 (previously amended) is further amended by this Amendment C.

Following entry of this Amendment C, Claims 2 (currently amended), 4,6,8 and 11 remain pending in the application.

REMARKS

Claims 1-13 were originally filed in the application. In response to a requirement for restriction, the undersigned, in a telephone conference conducted with the Examiner on 2/19/03, elected prosecution of claims 2,4,6,8 and 11 and withdrew claims 1,3,5,7,9,10 and 12-13 from further consideration. The election was confirmed by the applicant in Amendment B, dated June 6, 2003. Claims 2,4,6,8 and 11, as presently amended, remain pending in the present application.

SUMMARY OF THE INVENTION

A hybrid medical implant having a biocompatible, nonabsorbable core portion and a textured outer surface portion overlying the core portion wherein a portion of the outer surface portion is bioabsorbable. The hybrid implant is useful as a prosthesis for tissue augmentation and/or reconstruction. The core portion of the implant includes a body formed from a nonabsorbable, biocompatible implantable material such as silicone or urethane elastomer. The core portion may be either a solid body, a viscous gel body or a fluid-filled shell. The textured outer surface portion envelops the core portion and presents an irregular, textured surface to the exterior environment. The irregularities in the outer surface are due to a plurality of bioabsorbable particles embedded in a nonbioabsorbable elastomer comprising the outermost surface of the implant and projecting outwardly from the outermost surface of the nonbioabsorbable elastomer. Since the bioabsorbable particles are embedded in the (nonbioabsorbable) core, after disintegration of the bioabsorbable particles due to bioabsorption thereof by the hosts body, the character and topography of the outer surface changes, leaving a plurality of craters in the outer surface where the particles were embedded. The irregular topography of the outer surface of the hybrid implant in accordance with the present invention changes following implantation.

The Rejection Under 35USC§102

Claims 2,4,6,8 and 11 were rejected under 35 USC§102(e) as being anticipated by Harish et al. '437, and claims 2,4,6 and 8 were rejected as being anticipated by Durgin

published application No. US 2002/0052653 A1 (Durgin). Briefly, Harrish et al. '437 disclose an implantable device having "depots" formed in an outer surface thereof. The device includes an outer surface having pores or "depots" therein that are coated with a polymer (not particles) in a novel manner to reduce the presence of air bubbles in the depots. The polymer/solvent composition is not embedded in the outer surface of the core portion but applied uniformly to the outer surface thereof by dipping or spraying. This is set forth in '437 col. 8, lines 45-47. In another embodiment, the polymer composition is applied to the outer surface to fill the depots.

In contrast, the present invention discloses and claims a medical implant comprising a fluid-filled, nonbioabsorbable core enveloped by an outer shell that comprises a flexible nonbioabsorbable, nonporous elastomer, such as silicone elastomer, wherein the nonbioabsorbable elastomer has a plurality of bioabsorbable particles embedded therein and projecting outwardly from the outer surface of the outer shell and presenting an irregular topography. The method disclosed for adhering bioabsorbable particulates to an outer shell having an uncured silicone outer surface provides a medical implant having the structural and functional features recited in Claim 2 (Thrice Amended). Anticipation under 35 USC§102 requires that the cited references demonstrate each and every element of the claimed invention. In view of the differences between the elements of the present invention (i.e., the application of discrete particles to the outer surface), and those of the prior art (the applicatioin of a fluid coat to the outer surface) presented herein, it is requested that this rejection be withdrawn.

Claims 2,4,6 and 8 were rejected under 35 USC§102(e) as being anticipated by Durgin; published application No. US 2002/0052653 A1 (Durgin). Again briefly, Durgin

discloses an implant and a catheter operable for deploying the implant within the body. An embodiment of such an implant comprising bioabsorbable anchors 32A is shown in Figure 12, and described in paragraph [0056]. The anchors 32A are not embedded within the outer surface of the implant and do not form a crater in the outer surface of the implant when bioabsorbed following implantation. In Durgin, the anchors 32A are affixed to the outer surface of the implant. The purpose of the anchors 32A is to promote tissue ingrowth to prevent migration of the implanted device. The purpose of the bioabsorbable particles that are embedded in the outer surface of the present invention is to present an outer surface having an irregular topography to disrupt the structural organization of an autogenic capsule formed therearound following implantation and thereby reduce or prevent the contracture of the capsule.

As stated above in the discussion of Harish et al., in order for a patent to qualify as a reference supporting a §102 (b) rejection, it must disclose each and every limitation of the rejected claim. It is settled that even only slight differences between the compared inventions prevent a rejection based on lack of novelty under §102. Anticipation under 35 USC§102 requires that the cited references demonstrate each and every element of the claimed invention. In view of the differences between the elements of the present invention and those of the prior art presented herein, it is requested that this rejection be withdrawn.

The Rejection Under 35USC§103

Claims 2,6 and 8 were rejected under 35 USC§103(a) as being unpatentable over Marotta et al. '930 in view of Melican et al. '323. The Examiner argues that Marotta teaches substantially the present invention except that the Bioglass particles are

bioabsorbable but that since Melican et al. '323 teaches that Bioglass is bioabsorbable, it would be obvious to substitute bioabsorbable particles for the Bioglass taught by Marotta et al. '930. Applicant respectfully disagrees with the Examiner. Melican et al. '323 teaches an implant wherein the surface is textured to permit tissue ingrowth following implantation within a body. The texturing is provided by employing an (preferably bioabsorbable) open-celled foam body to form the outer layer of the implant; the pores or cells in the outer surface providing the texture and permitting tissue ingrowth. No portion of the Bioglass projects outwardly from the outer surface of the core. The purpose of the Bioglass is to reinforce the foam for mechanical strength while handling. The open-cell pores in the foam promote tissue ingrowth. There is no suggestion in '323 that particles of the reinforcing material (i.e., Bioglass) can or should be applied only to the outer surface of the implant to project outwardly therefrom or that there is any advantage to be gained from such a construction.

Marotta et al. '930 teach the advantage to be gained by the incorporation of nonbioabsorbable particles of Bioglass into the outer surface of an implant in order to reduce capsular contracture. It is noted that the term "Bioglass" is a trademark of the University of Florida, and used to describe "glassy" compositions that do not produce a fibrous capsule when implanted within a person. A further property of these materials is that they substantially adhere to both soft tissue and bone (hydroxyapatite). A definition of the term "Bioglass" or "biologically active glass" is provided by Marotta et al. '930 in col. 4, lines 61-65. The definition of Bioglass extends to particulate compositions that bond to tissue when implanted within the body. The purpose of the addition of Bioglass particulates to the outer surface of an impant in accordance with '930 is to improve tissue adhesion to

the implant. If the particles employed in '930 were bioabsorbable, the advantage of tissue adhesion would be lost. There is no mention or suggestion in '930 that the Bioglass particles may be bioabsorbable. In fact, such an interpretation of the teaching in '930 (i.e., that bioabsorbable particles could be used) would teach away from the purpose of the invention set forth in '930 and not be functional for the intended purpose.

The presently claimed invention discloses an outer shell wherein a portion of the shell is nonbioabsorbable and has a plurality of discrete, bioabsorbable particles embedded therein and projecting outwardly therefrom. In considering the question of obviousness of the claimed invention in view of the prior art relied upon, the applicant submits that the test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. The law requires an applicant to show only that the claimed combination of structure is non-obvious in view of the prior art under *Deere.* In summary, under *Deere*, to establish a *prima facie* case of obviousness of a particular claim, the Patent Office must :

(a) set forth differences in the claim over the applied references;

(b) set forth the proposed modification of the references which would be necessary to arrive at the claimed subject matter; and

(c) explain why the proposed modification would be obvious.

To satisfy step (c), the Patent Office must identify where the prior art provides a motivating suggestion to make the modifications proposed in step (b). In the present instance the combination of elements; specifically, a medical implant having a nonbioabsorbable core and a hybrid outer shell enveloping the core, wherein the hybrid outer shell comprises a nonbioabsorbable elastomer having a plurality of bioabsorbable

particles embedded therein, and projecting outwardly therefrom, as recited in independent claim 2 (currently amended), are different from the elements in the prior art and, moreover, are not suggested by the prior art. Marotta et al. 930 incorporate nonbioabsorbable "Bioglass" particles into the outer surface to improve tissue bonding and anchor the implant. Melican et al. '323 teaches the mechanical strengthening of a foam implant by the inclusion of particles, including Bioglass, therein. There is no suggestion in Melican et al. of an advantage to be gained by the embedding of bioabsorbable particles in the outer surface of an implant which project outwardly therefrom. There is no suggestion in Marotta et al. of an advantage to be gained by using bioabsorbable particles. In view these clarifications regarding the difference between the elements of the present invention and the prior art it is requested that this rejection be withdrawn.

The Rejection Under 35USC§112

The claims of the application have been carefully reviewed in light of the objections raised by the Examiner in the outstanding Office Action. Specifically, independent Claim 2 has been further amended to more particularly point out and distinctly claim features that applicant regards as the invention. Antecedent basis for all terms recited is provided in Claim 2 (currently amended). Applicant respectfully submits that the amended claims overcome the rejections under 35USC§112, and an indication to this effect is respectfully requested.

Entry of this amendment, reconsideration, favorable action and early allowance and publication of this application are respectfully requested. If there are any minor matters remaining, it is respectfully requested that the examiner contact the undersigned by phone

so that possible minor changes may be discussed in order to expedite the prosecution of this case.

Respectfully,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the following papers are being facsimile transmitted to the Patent and Trademark office on the date shown below.

1. Urgent and Time Sensitive Communication to the Examiner
2. Amendment C responsive to the Office Action dated 1/30/04.

Michael G. Petit

Date: April 26, 2004